

Joint B

WHAT IS CLAIMED IS:

1 1. A timed-release compression-coated solid composition for oral
2 administration, said composition comprising:
3 a) a core tablet comprising a drug and a freely erodible filler, wherein said
4 core tablet is capable of approximately 40 to approximately 90% erosion; and
5 b) an outer layer, said outlayer is made from a hydrogel-forming polymer
6 substance and a hydrophilic base, wherein said outer layer optionally contains a drug.

1 2. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the outer layer comprises a drug and wherein
3 the outer layer essentially does not contain the same drug as the core tablet drug.

1 3. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein there is approximately 75 wt% or less of said
3 drug, approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to
4 approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to
5 approximately 80 wt% hydrophilic base.

1 4. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more
3 selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene
4 glycol, sucrose, and lactulose. *or magent*

1 5. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more
3 selected from the group consisting of malic acid, citric acid and tartaric acid.

1 6. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or
3 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

1 7. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the freely erodible filler for an acidic or neutral
3 drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or
4 lactulose.

1 8. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrogel-forming polymer substance
3 contains at least one type of polyethylene oxide.

1 9. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrogel-forming polymer substance is 1 or
3 2 or more having a viscosity-average molecular weight of 2,000,000 or higher and/or a
4 viscosity in an aqueous 1% solution (25°C) of 1,000 cp or higher.

1 10. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the core tablet contains hydrogel-forming
3 polymer substance.

1 11. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having
3 solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.

1 12. The timed-release compression-coated solid composition for oral
2 administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected
3 from the group consisting of polyethylene glycol, sucrose, and lactulose.

1 13. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the hydrogel-forming polymer substance is at
3 least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric
4 oxide.

1 14. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is brought to be effectively released or
3 absorbed in the lower digestive tract.

1 15. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is brought to be effective for
3 chronopharmacotherapy.

1 16. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.

1 17. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein a drug has the effect of inhibiting metabolism
3 by cytochrome P-450.

1 18. The timed-release compression-coated solid composition for oral
2 administration according to claim 16, wherein the drug is metabolized by CYP3A4.

1 19. The timed-release compression-coated solid composition for oral
2 administration according to claim 17, wherein the drug has the effect of inhibiting
3 metabolism by CYP3A4.

1 20. The timed-release compression-coated solid composition for oral
2 administration according to claim 1, wherein the drug is 4'-(2-methyl-1,4,5,6-
3 tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

1 21. A method of timed release of a drug, whereby the composition in claim
2 1 is orally administered.

1 22. A method for alleviating undesirable drug interaction between a drug
2 and other drugs used concomitantly that employ the same route for drug absorption,
3 distribution, metabolism or excretion *in vivo* in humans, whereby the composition in claim 1
4 is orally administered.

1 23. A method of alleviating undesirable drug interaction with between a
2 drug having the effect of inhibiting drug metabolism *in vivo* in humans and another drug
3 according to claim 20 used concomitantly, whereby the composition in claim 1 is used.

1 24. In a hydrogel-forming compression-coated solid pharmaceutical
2 preparation comprising: a core tablet containing drug and outer layer made from hydrogel-
3 forming polymer substance and hydrophilic base, the improvement which comprises a timed-
4 release compression-coated solid composition according to claim 1.

1 25. In a hydrogel-forming compression-coated solid pharmaceutical
2 preparation comprising:

3 a core tablet containing drug and outer layer made from hydrogel-forming
4 polymer substance and hydrophilic base, the improvement which comprises a timed-release
5 compression-coated solid composition for oral administration, said composition comprising:
6 (1) a drug and freely erodible filler are mixed with the core tablet;
7 (2) the percentage erosion of the core tablet is approximately 40 to
8 approximately 90%; and
9 (3) the outer layer essentially does not contain the same drug as the above-
10 mentioned drug.

1 26. The timed-release compression-coated solid composition for oral
2 administration according to claim 25, wherein the drug is 4'-(2-methyl-1,4,5,6-
3 tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.